

APR 26 2001

K 010 283

510(k) Summary
Theragenics Corporation
TheraSeed® Palladium-103 Model 200 Implant

I. General Information on Submitter

Name: Theragenics Corporation
Address: 5203 Bristol Industrial Way
Buford, GA 30518
Phone: 770-271-0233
Fax: 678-482-4909

Name of Contact Person: Janet Zeman, Director of Regulatory Affairs
Theragenics Corporation
Phone: 770-271-0233
Fax: 678-482-4909

Date Summary Prepared: January 26, 2001

II. General Information on Device

Proprietary Name: TheraSeed® Palladium-103 Model 200 Implant
Common Name: Brachytherapy Source
Classification Name: Source, Radionuclide, Brachytherapy,
21 CFR §892.5730

III. Predicate Device

Theragenics Modified Palladium Seed Model 100
510(k) number K874787

IV. Description of Device

The TheraSeed® Palladium-103 Model 200 Implant consists of a laser welded titanium tube containing two palladium-103 plated graphite pellets and a lead x-ray marker.

V. Indications for Use

TheraSeed® Palladium-103 Implants are indicated for tumors with any of the following characteristics:

- Localized
- Unresectable
- Low to Moderate Radiosensitivity

The tumors may be of the following type:

- Superficial
- Intrathoracic
- Intra-abdominal
- Lung, Pancreas, Prostate, Head and Neck
- Residual Following External Beam or Excision of Primary Tumor
- Recurrent

VI. Technological characteristics of Device Compared to Predicate Device

The TheraSeed® Palladium-103 Model 200 Implant uses the same type of isotope and encapsulation as its predicate. There are no other safety and effectiveness differences between this device and its predicate.

VII. Substantial Equivalence

The TheraSeed® Palladium-103 Model 200 Implant has been tested for safety and effectiveness to its predicate TheraSeed® Palladium-103 Model 100 Implant by standard tests used for radionuclide devices. The TheraSeed® Model 200 Implant was found to be safe and effective and substantially equivalent to its predicate.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

APR 26 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Janet Zeman
Director, Regulatory Affairs
Theargenics Corporation
5203 Bristol Industrial Way
BUFORD WAY GA 30518

Re: K010283
Therased (R) Palladium-103 Model 200 Implant
Dated: January 26, 2001
Received: January 30, 2001
Regulatory Class: II
21 CFR §892.5730/Procode: 90 KXK

Dear Ms. Zeman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K010283

Device Name: TheraSeed(R) Palladium-103 Implant; Model 200

Indications For Use:

TheraSeed(R) Palladium-103 Implants are indicated for tumors with any of the following characteristics:

- * Localized
- * Unresectable
- * Low to Moderate Radiosensitivity

The tumors may be of the following type:

- * Superficial
- * Intrathoracic
- * Intra-abdominal
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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)


Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K010283